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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,333	08/20/2003	Bernd Disse	1/1196-1-C1	6665
28501	7590	06/29/2004	EXAMINER	
<b>BOEHRINGER INGELHEIM CORPORATION</b> 900 RIDGEURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877				KIM, VICKIE Y
		ART UNIT		PAPER NUMBER
		1614		

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/21

## Office Action Summary

Application No.	10/644,333	Applicant(s)	DISSE, BERND
Examiner	Vickie Kim	Art Unit	
		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 9-13 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/04.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Priority***

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) and 120 acknowledged. Also, acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/096810, filed on 03/13/2002.

### ***Status of Application***

2. The claims 9-13 are pending and presented for the examination.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Banholzer et al(US5,610,163).

Claims 9-13 are drawn to a method for treating pulmonary diseases such as chronic obstructive bronchitis and asthma using a salt of tiotropium(e.g. tiotropium bromide) via inhalation.

US'163 teaches a novel composition comprising anticholinergics including a salt of tiotropium(e.g. tiotropium bromide) and its use in the treatment of chronic bronchitis, chronic obstructive bronchitis and asthma, see abstract and claims, especially claims 1-5, 11-12 and 14. Furthermore, US'163 teaches the treatment is carried out effectively

via inhalation, see column 3, lines 27-37 and claims 122-14. Since bronchitis is a condition of chronic or acute inflammation of the mucous membrane of the bronchial tissue(tubes), the limitation recited in preamble of claim 9 is inherently met by the cited reference. For instance, the patented claim 5 teaches a compound of tiotropium.

Thus, all the critical elements required by the instant claims are well taught by the reference and all the claims are anticipated.

***Conclusion***

5. No claim is allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**VICKIE KIM**  
**PRIMARY EXAMINER**

Vickie Kim  
June 25, 2004  
Art unit 1614